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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,952	01/22/2002	Sujoy Kumar Guha	RS-01420	4417

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EXAMINER

MITCHELL, GREGORY W

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,952

Applicant(s)

GUHA, SUJOY KUMAR

Examiner

Gregory W. Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed January 24, 2004. Claims 30-43, 45-46 and 48 have been amended. Claims 55 and 56 have been added. Claims 30-56 are pending and are examined herein.

Claim Objections

Claim 33 is objected to because the phrase "wherein said ... material ... each being independently between ..." should read "wherein said ... material ... are each, independently, between ..."

Claim 36 is objected to because "wherein particle size of said microsize particles" should read "wherein the particle size of said microsize particles". Claim 36 is also objected to because "electrically" is misspelled as "electrically".

Claim 48 is objected to because the degree symbol between "35 C" has been removed and is missing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 36, 47-54 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is indefinite because it is unclear what "iron as at least one of iron oxide and a combination with a biologically accepted material ..." is meant to encompass. It is unclear if the iron is meant to be selected from iron oxide and iron in a composition with a biologically accepted material and if so, it is unclear whether or not the iron in the composition needs to be iron oxide. The claim may also mean that the iron is in an oxidative state. Furthermore, it is unclear what Applicant means by "like sulphur". Is the biological material "like" sulfur, or is it a material "such as" sulfur? If a material is "like" sulfur, does that mean that sulfur is excluded from the scope of the claim? Furthermore, how closely related to sulfur must the material be to be "like" sulfur?

Claim 36 is indefinite because there are no units for the upper limit of the range of the size of the macrosized particles.

Claim 47 is indefinite because neither the claim nor the claims from which it depends mentions anything about an external means or the purpose of said external means. Does Applicant intend to say that the contraceptive is detectable by the external means listed in the claim?

Claim 48 is indefinite because there is lack of antecedent basis for "said magnetic material" and "said solvent medium".

Claims 49-54 and 56 are rejected for depending from indefinite claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-47 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guha (USPN 5488075) in view of each of Young et al. (USPN 5817017), Riar, et al. (*Andrologia*, 1982, 14(6), 481), and Jakubek, et al. (GB 2 121 289 A).

Guha teaches the use of a styrene maleic anhydride copolymer with DMSO as a contraceptive (col. 1, lines 54-62). It is further taught that when injected into the vas deferens, the contraceptive copolymer hydrolyzes in the presence of water molecules in the spermatic fluid (col. 2, line 45-col. 3, line 7). Accordingly, it is Examiner's interpretation, that Guha teaches a composition comprising DMSO and a mixture of styrene maleic anhydride copolymer and the hydrolyzed copolymer thereof, namely styrene maleic acid copolymer.

Guha does not teach a composition further comprising a magnetic material and an electrically conducting material.

Young et al. teaches the use of magnetic particles within catheters and other medical devices, particularly those devices composed of organic polymers, for enhanced detectability when viewed using magnetic resonance imaging (col. 1, lines 26-57; col. 2, line 55-col. 5, line 59). Young et al. specifically teaches the use of small iron, including elemental iron and iron oxides, particles of a size less than 20 μm in catheters and other devices (col. 10, lines 42-63).

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Riar et al. teaches that copper deposited into the vasa deferentia of animals is effective at achieving a male contraception for 9 months (bottom of page 490-top of page 491).

Jakubek et al. teaches the use of a polymer mixed with 1 to 30% weight of a powdered metal, such as copper, as a contraceptive. The powdered metal is distributed throughout the polymer material and has a particle size of 2 to 50 μm . (Abstract.)

It would have been obvious to one of ordinary skill in the art to combine iron particles of a size less than 20 μm with the DMSO/polymer composition taught by Guha because, as taught by Young et al., iron particles are useful for enhancing magnetic resonance viewing of polymeric medical devices. Furthermore, it would have been obvious of one of ordinary skill in the art to add copper to the composition because it is obvious to one of ordinary skill in the art to combine two compositions each of which is taught by the prior art to be individually useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980). Therefore, it would have been obvious to combine copper particles in the size of 2 to 50 μm to the afore mentioned composition because (1) copper is known to be, itself, capable of contraception, as taught by Riar et al. and (2) polymeric contraceptives which include metallic components, such as copper, include said metallic components in particle sizes of 2 to 50 μm , as taught by Jakubek et al. It would have been obvious to incorporate the copper particles into the composition as claimed herein, because the weight percentage of the copper particles claimed herein fall within the range taught by Jakubek et al.

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One would have been motivated to combine iron and copper particles to the composition of Guha because of (1) an expectation of providing a means of locating said composition once it had been implanted into the body, as taught by Young et al., and (2) an expectation of success in preparing a composition capable of producing similar results in contraceptive behavior due to the ability of each component to individually affect contraception, as taught by Riar et al., respectively.

It is noted that since the macrosized particles are capable of being the same size as the microsize particles that a composition comprising particles of microsize, as defined by Applicant will, alone, meet the limitations of claims 37-39. It is also noted that a metal particles within a polymer composition will obviously be coated with that polymer. Furthermore, it is noted that Young et al. does not teach the desired weight percentage of the magnetic material. It is Examiner's position, however, that it would have been obvious to one of ordinary skill in the art to utilize the weight percentages of the magnetic material, as claimed herein, because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments/Amendments

Applicant's amendments are sufficient to overcome the 35 USC 112(2) rejections of claims 30-46 set forth in the Office Action dated September 22, 2004. The 35 USC 112(2) rejections of claims 47-54 are maintained, however, for the reasons set forth

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above. Furthermore, the amendments have necessitated the rejection of claims 32 and 36 under 35 USC 112(2).

Applicant's arguments that "hydrolysis of Styrene maleic anhydride in the presence of proteins and amino acids as is present in the lumen of the vas deferens of the male or the fallopian tube of the female will not produce Styrene maleic acid" are not persuasive. It is generally understood by the skilled artisan that the hydrolysis of an anhydride will produce the corresponding acid. Absent a showing to the contrary, it is Examiner's position that the hydrolysis of styrene maleic anhydride, as taught by Guha, would, necessarily, produce styrene maleic acid.

Applicant's argument that "if styrene maleic acid alone is added to styrene maleic anhydride without the electrically conducting material for charge transfer the styrene maleic acid would penetrate the mucosa as well as the muscular layers of the vas deferens causing harm particularly leading to fibrosis which will make reversal impossible" is not persuasive. It is not Examiner's position that it would have been obvious to *add* styrene maleic acid to the styrene maleic anhydride, but that the addition of an iron material and a copper material to the styrene maleic anhydride composition of Guha et al. would have been obvious considering the teachings of Young et al., Riar, et al., and Jakubek, et al. and that once such a composition was prepared, it would have, necessarily, produced the claimed composition *in vivo* because Guha et al. teaches that hydrolysis of the polymer is known to occur once injected.

Applicant's argument that Young et al. limits the use of iron particles in the patient's body to MRI is not persuasive. Applicant's claims are not directed to a method

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of detecting the contraceptive, but to the contraceptive composition itself. Accordingly, the fact that the motivation to add the paramagnetic particles to the composition is limited only to the detection of the composition by MRI is immaterial because the motivation provided by the prior art to arrive at the same composition need not be the same as Applicant's. Furthermore, it is noted that none of Applicant's claims indicate that the material must be detectable by *all* recited means. Finally, it is noted that since the addition of the magnetic material would have been obvious for the reasons stated above, the same composition will, obviously, have the same properties as the composition claimed.

Applicant's arguments that "Riar et al. uses copper for its chemical properties embedded in the vas deferens wall. The present patent applicant uses 'electrically conducting material' which could be material other than copper" is not persuasive. It is noted that copper is not excluded as a claimed electrically conducting material. Accordingly, since it would have been obvious to add copper to the composition, the claim limitation is met. It is noted that the claims are not directed to a method of removing the contraceptive, but to the contraceptive composition itself. Accordingly, the motivation of the prior art to combine the materials need not be the same as Applicant's.

Applicant's argument that "Jakubek et al. covers use as an intrauterine device. The disclosure does not teach any usage in the fallopian tube" is not persuasive. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

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1986). Jakubek et al. is merely used to show that it is known in the art to incorporate copper into a polymeric matrix for contraceptive uses. Riar et al. is used to teach a contraceptive comprising copper for use in the vasa deferentia. Furthermore, it is noted that the intended use of the composition, i.e. for injection into the vas deferens, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicant's arguments that "Jacubek's disclosure does not teach heating of the copper for removal" are not persuasive because the invention is directed to a composition, not to a method of removal.

Applicant's arguments that "neither Guha, Young et al., Riar et al. nor Jakubek et al. teach or suggest the use of chemicals such as styrene maleic acid or copper as they are used in the present invention" is not persuasive because, as explained above, the intended use of a composition is immaterial so long as the composition rendered obvious by the prior art is capable of performing the intended use.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

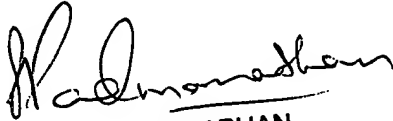
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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm